

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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In re Patent Application of: Inge Dorthe Hansen

Application No.: 10/560,519

Confirmation No.: 5664

Filed: March 20, 2006

Art Unit: 1623

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For: TREATMENT OF SYMPTOMS ASSOCIATED  
WITH BACTERIAL VAGINOSIS

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Examiner: M. C. Henry

**PRE-APPEAL BRIEF ARGUMENTS**

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

In response to the final Office Action mailed August 20, 2008, Appellant hereby submits a Notice of Appeal accompanied by a Pre-Appeal Request for Review. Pre-Appeal Brief arguments are set forth below for the consideration of the review panel.

**The Rejection of Claims 30-61 Under 35 U.S.C. §112, Second Paragraph**

Independent claims 30, 53 and 58 stand rejected under 35 U.S.C. §112, second paragraph because the Examiner finds it “unclear whether or not a gel or suspension that comprises at least 75% by weight of said saccharide (as recited in b) is not considered a medicament which comprises at least 75% by weight of said saccharide (as recited in a).”

Appellant respectfully submits that the claims in their present form are clear. There is no apparent ambiguity in the expression of the compositions of the medicaments described in a) and b) of these claims. It is clear that a gel or suspension comprising at least 40% by weight of said saccharide can, of course, include more than 40% of the saccharide and that a gel or suspension comprising at least 75% of the saccharide falls within the scope of both a) and b).

It is submitted that that one of skill in the art could understand the metes and bounds of the claims. In view of Appellant's belief in the clarity of these independent claims, it is respectfully requested that the rejection of claims 30, 53, and 58 be withdrawn.

Appellant presumes, although the Examiner has not explicitly so stated, that claims 31-52 and 54-57 are rejected under 35 U.S.C. §112, second paragraph due to dependence on independent claims 30, 53 or 58. In view of Appellant's belief in the clarity of the independent claims, it is respectfully requested that the rejection of these claims be withdrawn as well.

The Examiner further rejects independent claim 59 and dependent claims 60-61. Although not explicitly stated in the Final Office Action, Appellant presumes that independent claim 59 is likewise rejected for the reasons described for independent claims 30, 53 and 58, and Appellant submits that this claim and claims 60-61 which depend therefrom are clear and respectfully requests that the rejection of these claims be withdrawn as well.

Dependent claim 36 stands separately rejected under 35 U.S.C. §112, second paragraph. In an "Amendment After Final Action Under 37 C.F.R. 1.116" filed on December 11, 2008, Appellant canceled claim 36 and therefore submits that this rejection is moot.

**The Rejection of Claim 58 Under 35 U.S.C. §112, First Paragraph**

In an "Amendment After Final Action Under 37 C.F.R. 1.116" filed on December 11, 2008, Appellant canceled claim 58 and therefore submits that this rejection is moot.

**The Rejection of Claims 53-57 Under 35 U.S.C. §103(a)  
Over Woitun et al. (DE 1959402 A)**

Independent claim 53 and claims 54-57 are rejected as obvious over Woitun et al. (DE 1959402 A).

Independent claim 53 describes pharmaceutical compositions for vaginal application comprising a saccharide and less than  $10^5$  bacteria per dosage, wherein the composition includes a) at least 75% by weight of the saccharide or b) wherein the composition is a gel or suspension and includes at least 40% by weight of the saccharide.

In contrast, the Woitun et al. reference teaches various compositions of which only one, described in Example III, appears to be for vaginal application. Appellant notes that the sole

composition described in Example III does not appear to include a saccharide. Thus, the reference does not appear to teach or suggest all aspects of the present claims.

The Examiner states that “it is obvious to prepare Woitun et al.’s composition in different percent or amounts of saccharide or bacteria based on factors such as the type and severity of the symptom or condition and type and age of the individual treated.”

Appellant submits there is simply no basis for this assertion. One of skill in the art has no motivation to adjust the percent or amounts of saccharide or bacteria given the teachings of Woitun et al. On the contrary, the Woitun et al. reference refers to 2-(5-nitro-2-furyl)-4-hydroxy-thieno 3,2-d pyrimidines as the active ingredients in the described compositions. No reference to bacteria content of the Woitun et al. compositions is apparent. It appears that this element is contributed by Appellant’s specification and the rejection therefore is based on the use of impermissible hindsight.

Appellant submits that there is no basis for the present obviousness rejection and no prima facie case of obviousness is established. Withdrawal of the rejection and allowance of the claims is respectively requested.

**The Rejection of Claims 30-48, 51-52 and 59-61 Under 35 U.S.C. §103(a)**  
**Over Ozemen et al. (Turkish Journal of Medical Sciences)**

Claims 30-48, 51-52 and 59-61 stand rejected over Ozemen et al. (Turkish Journal of Medical Sciences (1998), 28(2), pp. 171-173).

Independent claims 30 and 59 describe methods including administering a medicament including a saccharide and less than  $10^5$  bacteria per dosage, wherein the medicament includes a) at least 75% by weight of the saccharide or b) wherein the composition is a gel or suspension and includes at least 40% by weight of the saccharide.

The Examiner states that “[t]he difference between Appellant’s claimed method and the method of Ozmen et al. is the percent or amount of saccharide in the composition.” (Paper No.20080813, p.10, last para.) It is asserted that “it is obvious to prepare and administer Ozmen et al.’s compositions comprising different percent or amounts of saccharide and bacteria based

on factors such as the type and severity of the symptom or condition and type and age of the individual treated.” (Paper No.20080813, p.10, last para.)

Appellant notes that administration of bacteria appears to be asserted as the basis of therapeutic effects seen using methods and compositions described in Ozmen et al. For example, Ozmen et al. states that they “conducted a randomized trial to compare the effects of three different treatment modalities (oral metronidazole, oral metronidazole plus locally administered lyophilised lactobacilli, and only locally administered lyophilized lactobacilli) on the course of bacterial vaginosis.” (p.171, right column) The Ozmen et al. reference describes administration of doses of Lactobacillus acidophilus “containing at least  $10^7$  to  $7 \times 10^8$  viable microorganisms...” (p.172, left column, 1<sup>st</sup> full para.) This is in contrast to the present claims which describe administration of a medicament which includes less than  $10^5$  bacteria per dosage. It is noted that this dosage is considered to be substantially free from bacteria, as stated in the present specification, p.6, lines 16-25. Appellant submits that there is no reasonable basis for an assertion of obviousness since the Ozmen et al. reference directly teaches away from compositions and methods which are substantially free from bacteria. One of skill in the art would find no motivation to reduce the therapeutic dose of microorganisms of Ozmen et al. by 100-fold or more.

Appellant submits that there is no basis for the present obviousness rejection and no prima facie case of obviousness is established with regard to independent claims 30 and 59. In view of Appellant’s belief as to the allowability of the independent claims, dependent claims 31-48, 51-52 and 60-61 are likewise submitted to be allowable. Withdrawal of the rejection and allowance of the claims is respectively requested.

**The Rejection of Claims 49-50 Under 35 U.S.C. §103(a) Over Ozemen et al.**  
**(Turkish Journal of Medical Sciences**  
**in Combination with Lin et al. (US 2003/0017207 A1)**

Dependent claims 49 and 50 stand rejected over Ozemen et al. (Turkish Journal of Medical Sciences (1998), 28(2), pp. 171-173) in combination with Lin et al. (US 2003/0017207 A1)

As described above, Appellant submits that there is no basis for the obviousness rejections based on the Ozmen et al. reference and no prima facie case of obviousness is believed to be established with regard to independent claim 30. In view of Appellant's belief as to the allowability of the independent claim, dependent claims 49-50 are likewise submitted to be allowable. Withdrawal of the rejection and allowance of the claims is respectively requested.

Dated: Dec. 11, 2008

Respectfully submitted,

By 

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